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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,004

10/21/2003

Ajitkumar B. Nair

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09/14/2006

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,004

Applicant(s)

NAIR ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-32 and 37-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/04 & 2/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 33-36, in the reply filed on 31 August 2006 is acknowledged.
2. Claims 1-32 and 37-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 31 August 2006. The requirement is made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 33, 34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (European Patent No. 0 200 668).

Regarding claim 33, Fogarty et al. disclose a system comprising a device (Figure 2, elements 20 and 14) for trapping and removing an occlusive object (10) from a body passage (12). Fogarty et al. further disclose an elongated shaft (24) having a proximal section (not labeled) and a distal section (not labeled; end closer towards port 30), an inflation lumen (Figure 11, element 38) extending from the proximal section of the elongated shaft (24) to the distal section (see Figure 11) of the elongated shaft (24), a retrieval lumen (36) configured to receive at least part of the intravascular device (for

example, portion 20; see Figure 6), and an expandable sleeve (Figure 3, element 16) disposed about the distal section of the elongated shaft (24) in fluid communication with the inflation lumen (via port 30).

The preamble "A system for retrieving a blood clot disposed at a target site within a blood vessel" is given limited weight and the device disclosed by Fogarty et al. is inherently capable of performing the function as claimed. Fogarty et al. disclose the device is used for retrieving a foreign object in a body passage. Therefore, the device disclosed by Fogarty et al. is inherently capable of retrieving a blood clot (a foreign object) within a blood vessel (a body passage). Furthermore, the balloon catheter (comprised of elements 24, 36, 38, and 16) is inherently configured to intussuscept the intravascular device (20/14) and blood clot (foreign object) while limiting the proximal flow of blood within the blood vessel (Figure 2 shows a seal between body passage 12 and the balloon catheter when sleeve 16 is inflated, thus being capable of limiting blood flow if body passage 12 is a blood vessel).

Regarding claim 34, Figures 3-6 show the expandable sleeve (16) is configured to unfold distally (distal end of sleeve 16 is not labeled) when inflated (Figure 6 shows distal end "unfolds" when inflated as sleeve 16 engulfs foreign object 10).

Regarding claim 36, Figure 2 shows the expandable sleeve is configured to radially and axially expand to a pre-defined shape (Fogarty et al. also disclose elastic or inelastic material may be used to form expandable sleeve 16; column 5, lines 33-37).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al. in view of Hardwick (Patent No. 4,469,100).

Fogarty et al. disclose the device described above, wherein the expandable sleeve is configured to unfold distally (Figure 6 shows distal end "unfolds" when inflated as sleeve 16 engulfs foreign object 10). However, Fogarty et al. do not disclose an adhesive layer disposed about a portion of the elongated shaft. Like Fogarty et al., Hardwick disclose an intussuscepting balloon catheter (Figure 5). Unlike Fogarty et al., Hardwick teaches an adhesive layer (column 4, lines 44-46) disposed about a portion of the elongated shaft (at portion 19; see Figure 6) in order to bond or fuse the sleeve (16) to the elongated shaft (10), thus forming a closed balloon that can be inflated (column 4, lines 61-64). Therefore, to dispose an adhesive layer about a portion of the elongated

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shaft of the device of Fogarty et al. as taught by Hardwick would have been obvious to one of ordinary skill in the art at the time the invention was made in order to bond the sleeve to the elongated shaft, thus enabling inflation of the sleeve.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson 
September 5, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
